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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,744	03/05/2002	Andrew Holman	020862-000110US	8465

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EXAMINER	
CRIARES, THEODORE J	

ART UNIT	PAPER NUMBER
1617	8

DATE MAILED: 10/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/091,744	Applicant(s) HOLMAN, ANDREW	
	Examiner Theodore J. Criares	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *30-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

CLAIMS 1-39 ARE PRESENTED FOR EXAMINATION

Applicant's response filed August 1, 2003, implies that the Restriction Requirement of June 30, 2003 was unclear and requested reconsideration of the restriction under 35 U.S.C. 121 to achieve a proper, compact and expedited prosecution of the present invention.

In view of the above reconsideration has the following effect:

Applicant's traversal is not persuasive since a method of using a composition is in fact different than the composition per se and in light of the present claims an undue burden is placed on the examiner. Further, it is not a practice in the pharmaceutical art to allow a composition with method of use unless the composition falls within the scope of the method claims. Rejoinder is allowable if the facts of the application deem it proper.

Claims 30-39 are withdrawn from consideration, but are subject to rejoinder.

This application contains claims 1-29, which are to be considered, directed to the following patentably distinct species of the claimed invention:

GROUP I - A method for sparing an effective amount of a therapeutic agent administered to a subject having rheumatoid arthritis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP II — A method for sparing an effective amount of a therapeutic agent administered to a subject having psoriatic arthritis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP III – A method for sparing an effective amount of therapeutic agent administered to a subject having a spondyloarthropathy by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP IV-A method for sparing an effective amount of therapeutic agent administered to a subject having palindromic rheumatism by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP V – A method for sparing an effective amount of therapeutic agent administered to a subject having systemic lupus erythematosus by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP VI- A method for sparing an effective amount of therapeutic agent administered to a subject having vasculitis with systemic lupus erythematosus by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP VII – A method for sparing an effective amount of therapeutic agent administered to a subject having multiple sclerosis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP VIII – A method for sparing an effective amount of therapeutic agent administered to a subject having Hashimoto's thyroiditis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP IX – A method for sparing an effective amount of therapeutic agent administered to a subject having chronic pseudogout by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP X – A method for sparing an effective amount of therapeutic agent administered to a subject having hepatitis C arthritis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XI – A method for sparing an effective amount of therapeutic agent administered to a subject having mixed connective tissue disease by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XII – A method for sparing an effective amount of therapeutic agent administered to a subject having dermatomyositis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XIII – A method for sparing an effective amount of therapeutic agent administered to a subject having polymyositis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XIV – A method for sparing an effective amount of therapeutic agent administered to a subject having scleroderma by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XV – A method for sparing an effective amount of therapeutic agent administered to a subject having Sjogren's syndrome by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XVII – A method for sparing an effective amount of therapeutic agent administered to a subject having cryoglobulinemia by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XVIII – A method for sparing an effective amount of therapeutic agent administered to a subject having Crohn's disease by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XIX – A method for sparing an effective amount of therapeutic agent administered to a subject having ulcerative colitis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XX – A method for sparing an effective amount of therapeutic agent administered to a subject having autoimmune hepatitis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXI – A method for sparing an effective amount of therapeutic agent administered to a subject having sclerosing cholangitis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXII – A method for sparing an effective amount of therapeutic agent administered to a subject having primary biliary cirrhosis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXIII – A method for sparing an effective amount of therapeutic agent administered to a subject having autoimmune pneumonitis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXIV – A method for sparing an effective amount of therapeutic agent administered to a subject having autoimmune cerebritis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXV – A method for sparing an effective amount of therapeutic agent administered to a subject having thyroiditis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXV I– A method for sparing an effective amount of therapeutic agent administered to a subject having graft versus host disease by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXVI – A method for sparing an effective amount of therapeutic agent administered to a subject having Myasthemia gravis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXVII – A method for sparing an effective amount of therapeutic agent administered to a subject having pemphigus vulgaris by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXVIII – A method for sparing an effective amount of therapeutic agent administered to a subject having temporal arteritis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXIX – A method for sparing an effective amount of therapeutic agent administered to a subject having polymyalgia rheumatica by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXX – A method for sparing an effective amount of therapeutic agent administered to a subject having autoimmune hemolytic anemia by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXXI – A method for sparing an effective amount of therapeutic agent administered to a subject having idiopathic thrombocytopenic purpura by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXXII – A method for sparing an effective amount of therapeutic agent administered to a subject having thrombotic thrombocytopenic purpura by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXXII A method for sparing an effective amount of therapeutic agent administered to a subject having hemolytic uremic syndrome by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXXIII – A method for sparing an effective amount of therapeutic agent administered to a subject having Sweet's symdrome by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXXIV – A method for sparing an effective amount of therapeutic agent administered to a subject having polyarteritis nodosa by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXXIV – A method for sparing an effective amount of therapeutic agent administered to a subject having microscopic polyarteritis nodosa by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXXV – A method for sparing an effective amount of therapeutic agent administered to a subject having amyloidosis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXXVI – A method for sparing an effective amount of therapeutic agent administered to a subject having sarcoidosis by administering a therapeutic agent and an effective amount of a sleep restorative agent.

GROUP XXXVII – A method for sparing an effective amount of therapeutic agent administered to a subject having familial Mediterranian fever by administering a therapeutic agent and an effective amount of a sleep restorative agent.

The methods of claims 1-29 require the administration of two active agents which has the following effect:

This application contains claims directed to the following patentably distinct species of sleep restorative and therapeutic agents which can be administered in the claimed elected invention:

1 Sleep restorative agents as claimed in claim 8 wherein the species have radicals attached to the moiety that are:

a) acyclic

b) pyrrolidino.

c) piperidino.

d) hexamethyleneimino

e) morpholino

2. Sleep restorative agents as claimed in claim 10.

3. Therapeutic agents:

i. TNFα receptor.

ii. Methotrexate

iii. Prednisone

iv. An interferon

v. A cyclosporin

vi. An ascomycin

vii. A rapamycin

viii. A corticosteroid

ix. A cyclophosphamide

x. Azathioprine

xi. Brequinar

xii. Leflunomide

xiii. Mizoribine

xiv. Deoxyspergualin

xv. An immunosuppressive monclonal antibodie to a leukocyte receptor

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species relating to a method and a single combination of a sleep restorative agent and a therapeutic agent for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is required to elect a single

therapeutic agent for the species under I-ix and xv for examination purposes. Currently, claims 1, 8, 10 and 22 are generic.

The methods of claims 1-29 require the administration of two agents

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-

4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Theodore J. Criares
Primary Examiner
Art Unit 1617

10/08/03
tjc